

**REMARKS**

Claims 1-16 are currently pending. Claims 1 and 16 have been amended, and new claim 17 has been added. Support for the amendment to claim 1 can be found throughout the specification, including, for example, on pages 1-2, page 9, lines 18-21, page 11, line 20 to page 12, line 6, and page 18, line 28 to page 20, line 13. Support for the amendment to claim 16 and for new claim 17 can be found in the specification on page 15. Applicants respectfully request reconsideration and allowance of all pending claims.

**1. Rejection of the claims under 35 U.S.C. §112, First Paragraph**

Reconsideration is requested of the rejection of claim 1-16 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office states that there is no support in the specification for identifying, evaluating, or measuring the need of an infant to increase lean body mass and reduce fat body mass.

Although applicants disagree with the Office's position, as noted above, claim 1 has been amended to remove the limitation "identifying a need to increase lean body mass and reduce fat body mass in the infant," and to instead require the infant be fed the nutritional formula "for the purpose of increasing lean body mass and reducing fat body mass in the infant." Support for this requirement is found throughout the specification, for example, on pages 1-2, page 9, lines 18-21, page 11, line 20 to

page 12, line 6, and page 18, line 28 to page 20, line 13. In particular, the specification indicates that the method of the present invention "comprises feeding to an infant, preterm or term, a nutritional formula having the requisite DHA and ARA components as described herein, to provide the infant with reduced body fat weight and increased lean body weight over time without impacting total overall growth."<sup>1</sup>

MPEP §2163 states that the first paragraph of 35 U.S.C. §112 requires that the "specification shall contain a written description of the invention...To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." Furthermore, subject matter that is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. Specifically, if a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly describe in the specification, then the adequate description requirement is met.<sup>2</sup>

In light of the foregoing, applicants submit that the specification sufficiently describes feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass

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<sup>1</sup> See Specification at page 9, lines 18-21 (emphasis added).

<sup>2</sup> See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed.

in the infant such that one skilled in the art could reasonably conclude that the inventors had possession of the claimed invention. Applicants thus request the rejection of claims 1-16 under 35 U.C.C. 112, first paragraph be withdrawn.

**2. Rejection of the Claims under 35 U.S.C. §102(b) over O'Connor, et al.**

Reconsideration is requested of the rejection of claims 1-14 under 35 U.S.C. §102(b) as being anticipated by O'Connor, et al. (U.S. Application Publication No. 2002/0045660).

As amended, claim 1 is directed to a method of increasing lean body mass and reducing fat body mass in infants. The method comprises feeding the infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant.

O'Connor, et al. is directed to "[m]ethods for providing nutrition and for enhancing neurological development of preterm infants," and to "an improved nutritional composition containing specified amounts of [docosahexaenoic acid (DHA)] and [arachidonic acid (ARA)] as well as their precursor essential fatty acids alpha-linolenic and linoleic acids."<sup>3</sup> The method comprises feeding infants nutrient-enriched formulas supplemented with long chain polyunsaturated fatty acid, including both DHA and ARA, for an extended feeding regimen, typically at least three months corrected age, and preferably to

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Cir. 1991); *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972).

6 or 12 months corrected age.<sup>4</sup> O'Connor, et al. state that the methods described therein do not result in growth inhibition of the infants, such as that previously observed when DHA without ARA was used, and also result in improved or enhanced neurological development, such as visual, motor, and language development.<sup>5</sup>

Significantly, O'Connor, et al. fail to disclose or suggest feeding a nutritional formula comprising a source of DHA and ARA to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by amended claim 1. As noted above, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, but do not disclose or suggest that such formulas have any effect on body composition, such as increasing lean body mass and reducing fat body mass.

In the Response to Arguments section of the current action, the Office has stated that limitations relating to identifying a need to administer any particular formula is inherently described in O'Connor, et al., since no parents can change an infant's formula to a special kind of formula without advice from a person skilled in the art who would not make the decision unless the infant is evaluated. The Office also states that claiming a new use, new function, or unknown property which is inherently present in the art does not necessarily make the

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<sup>3</sup> O'Connor, et al. at abstract.

<sup>4</sup> *Id.*

claim patentable. Applicants' respectfully disagree with the Office's position.

Initially, applicants note that a finding of inherency cannot be based on *mere assumptions* by the Office. Rather, to establish inherency, "the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art."<sup>6</sup> Furthermore, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."<sup>7</sup>

In the instant case, amended claim 1 requires the nutritional formula comprising a source of DHA and ARA be fed to the infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. The Office has pointed to nothing in O'Connor, et al. to suggest that the methods of O'Connor, et al. inherently require feeding the formulas disclosed therein to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. As noted above, at best, O'Connor, et al. disclose administering the ARA and DHA supplemented formulas described therein for the purpose of improving or enhancing neurological development, such

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<sup>5</sup> *Id.* at paragraphs 64 and 66.

<sup>6</sup> MPEP §2112 (citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)).

<sup>7</sup> MPEP §2112 (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993)). MPEP §2112 also states "[i]nherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

as visual, motor, and language development, in an infant, but say nothing about their formulas having any effect on body composition, such as lean body mass and fat body mass, in the infant.

As noted above, the Office has stated that limitations relating to identifying a need to administer any particular formula is inherently described in O'Connor, et al. since no parents can change an infant's formula to a special kind of formula without advice from a person skilled in the art who would not make the decision unless the infant is evaluated. Applicants respectfully disagree, and submit that these statements do not support the Office's assertion of inherency. Specifically, applicants note that numerous types of infant nutritional formulas are commercially available to parents, which comprise different components and which are labeled as having different nutritional and health benefits for infants. Parents can, and often do, readily change the type of nutritional formula they feed to their child without the specific advice of a person skilled in the art and without prior evaluation of the infant as to the need to change formulas. In the instant case, what is relevant is that there is no disclosure, either expressly or inherently, in the O'Connor, et al. reference of feeding a nutritional formula comprising a source of DHA and ARA to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. The mere fact that O'Connor, et al. disclose administering a nutritional composition comprising a source of ARA and DHA to an infant does not mean O'Connor, et al. inherently (i.e.,

necessarily) disclose administering the composition for all purposes, or more specifically, for the purpose of increasing lean body mass and reducing fat body mass in the infant.

Further, as noted above, the Office has asserted that claiming a new use, new function, or unknown property which is inherently present in the art does not necessarily make the claim patentable. Applicants submit, however, that whether or not the nutritional formulas of O'Connor, et al. inherently result in an increase in lean body mass and a reduction in fat body mass when fed to an infant is irrelevant to determining if O'Connor, et al. inherently discloses applicants' claimed method. As noted above, applicants' amended claim 1 specifically requires the nutritional formula comprising a source of DHA and ARA be administered to the infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. Thus, in order to anticipate applicants' claim 1, O'Connor, et al. must also disclose, either expressly or inherently, a method wherein a nutritional formula comprising a source of DHA and ARA is administered to the infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. For the reasons set forth above, there is clearly no disclosure or suggestion in O'Connor, et al. of administering the nutritional formulas disclosed therein for this purpose.

As stated in MPEP §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art

reference. Since O'Connor, et al. fail to disclose feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, and generally fail to disclose or suggest that the formulas disclosed therein have any affect on body mass, O'Connor, et al. fail to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 2-14 depend from claim 1 and are thus patentable over O'Connor, et al. for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

New claim 17 is directed to a method of increasing lean body mass and reducing fat body mass in infants. The method comprises feeding the infant a nutritional formula comprising a source of DHA and ARA; and evaluating the lean body mass and fat body mass of the infant after feeding the infant the nutritional formula. O'Connor, et al. fail to disclose or suggest evaluating the lean body mass and fat body mass of an infant after feeding the infant the formulas disclosed therein. Claim 17 is thus also patentable over O'Connor, et al.

**3. Rejections of the Claims under 35 U.S.C. §102(b) over Koletzko**

Reconsideration is requested of the rejection of claims 1, 5, and 11 under 35 U.S.C. §102(b) as being anticipated by



Koletzko ("Fatty acids and early human growth," Am. J. Clin. Nutr., 2001, Vol. 73:671-2).

Koletzko describes various studies evaluating the relationship between long-chain polyunsaturated fatty acids, and early human growth. Koletzko notes that there is a possible relationship between the supply and metabolism of different fatty acids and early human growth. Koletzko further states that the provision of infant formulas with a balanced supply of dietary arachidonic acid and docosahexaenoic acid in reasonable amounts and with adequate antioxidant protection, which is recommended by many experts worldwide, did not lead to poor growth or other adverse effects in several randomized clinical trials. Koletzko further notes that the quality of maternal dietary fat consumption before and during pregnancy and lactation is of considerable importance for infants.<sup>8</sup>

Significantly, Koletzko fails to disclose or suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by amended claim 1. Nor does Koletzko generally recognize or suggest that formulas comprising ARA and DHA increase lean body mass and reduce fat body mass. Rather, as noted above, Koletzko merely states that infant formulas with a balanced supply of dietary ARA and DHA did not lead to poor growth or other adverse effects in several randomized clinical studies.

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<sup>8</sup> See Koletzko at p. 672.

In the Response to Arguments section of the current action, the Office has stated that administering the same formula to the same population should produce the same results and, as such, even if Koletzko does not literally disclose limitations relating to increasing lean body mass and reducing fat body mass in an infant, the reference clearly teaches that the formula enhances health growth. Applicants' respectfully disagree with the Office's position.

Specifically, whether or not a nutritional formula comprising a source of DHA and ARA inherently results in an increase in lean body mass and a reduction in fat body mass when fed to an infant is irrelevant to determining if Koletzko discloses applicants' claimed method. As noted above, applicants' amended claim 1 specifically requires a nutritional formula comprising a source of DHA and ARA be administered to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. Thus, in order to anticipate applicants' claim 1, Koletzko must also disclose, either expressly or inherently, a method wherein a nutritional formula comprising a source of DHA and ARA is administered to an infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. There is, however, clearly no such disclosure or suggestion in Koletzko. As noted above, at best Koletzko discloses that infant formulas with a balanced supply of dietary ARA and DHA in reasonable amounts and with adequate antioxidant protection, did not lead to poor growth or other adverse effects in several randomized clinical trials. There is nothing in Koletzko that suggests that ARA and

DHA increase lean body mass and decrease fat body mass in infants.

Since Koletzko fails to disclose feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, Koletzko fails to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 5 and 11 depend from claim 1 and are thus patentable over the cited reference for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Additionally, with regard to new claim 17, applicants submit that Koletzko fails to disclose or suggest evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising a source of DHA and ARA. Claim 17 is thus also patentable over Koletzko.

**4. Rejections of the Claims under 35 U.S.C. §102(b) over Innis, et al.**

Reconsideration is requested of the rejection of claims 1, 5, and 10 under 35 U.S.C. §102(b) as being anticipated by Innis, et al. ("Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in preterm infants fed formula," J. Pediat., May 2002, Vol. 140, No. 5, pp. 547-54).

Innis, et al. describe a study testing the effects of DHA and ARA supplementation on growth or visual acuity of formula-

fed premature infants. Specifically, the Innis, et al. study gave premature infants preterm formula with either no DHA or ARA (control), 0.15% energy DHA, or 0.14% DHA plus 0.27% ARA from single-cell triglycerides for at least 28 days, and then fed the infants term formula (with no DHA or ARA) to 57 weeks postmenstrual age. The results of the Innis, et al. study found that infants fed the DHA plus ARA formula gained weight significantly faster during preterm formula feeding than control infants, had weights and weight:length ratios not different from term breast-fed infants at 48 and 57 weeks PMA, and that providing DHA or DHA plus ARA during the preterm period had no effect on subsequent visual acuity or incidence of adverse events. Innis, et al. concluded that feeding DHA plus ARA from single-cell triglycerides enhances weight gain in formula-fed premature infants with no evidence of adverse effects.<sup>9</sup>

Significantly, Innis, et al. fail to disclose or suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant. Nor do Innis, et al. generally recognize or suggest that formulas comprising ARA and DHA increase lean body mass and reduce fat body mass. Rather, as noted above, Innis, et al. merely evaluated the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants.

In the Response to Arguments section of the current action, the Office has again stated that administering the same formula

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<sup>9</sup> See Innis, et al. at abstract.

to the same population should produce the same results and, as such, even if Innis, et al. do not literally disclose limitations relating to increasing lean body mass and reducing fat body mass in an infant, the reference clearly teaches that the formula enhances healthy growth. Applicants' respectfully disagree with the Office's position.

Specifically, as discussed above, whether or not a nutritional formula comprising a source of DHA and ARA inherently results in an increase in lean body mass and a reduction in fat body mass when fed to an infant is irrelevant to determining if Innis, et al. disclose applicants' claimed method. As noted above, amended claim 1 specifically requires a nutritional formula comprising a source of DHA and ARA be administered to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. Thus, in order to anticipate applicants' claim 1, Innis, et al. must also disclose, either expressly or inherently, a method wherein a nutritional formula comprising a source of DHA and ARA is administered to an infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. There is, however, clearly no such disclosure or suggestion in Innis, et al. As noted above, at best Innis, et al. merely evaluate the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants. There is nothing in Innis, et al. that suggests that ARA and DHA have any affect on body composition, or more specifically, that ARA and DHA increase lean body mass and decrease fat body mass in infants.

Since Innis, et al. fail to disclose feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, Innis, et al. fail to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 5 and 10 depend from claim 1 and are thus patentable over the cited reference for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Additionally, with regard to new claim 17, applicants submit that Innis, et al. fail to disclose or suggest evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising a source of DHA and ARA. Claim 17 is thus also patentable over Innis, et al.

**5. Rejection of the Claims under 35 U.S.C. §103(a)**

Reconsideration is requested of the rejection of claims 1-16 under 35 U.S.C. §103(a) as being unpatentable over Innis, et al. ("Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in preterm infants fed formula," J. Pediat., May 2002, Vol. 140, No. 5, pp. 547-54) in view of Koletzko, et al. ("Physiological aspects of human milk lipids," Early Human Development, 2001, 65 Suppl.:S3-S18), and further in view of O'Connor, et al. (U.S. Patent Application No. 2002/0045660).

Innis, et al. and O'Connor, et al. are discussed above. As previously discussed, Innis, et al. and O'Connor, et al. both fail to disclose or suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant.

Koletzko, et al. discuss the physiological aspects of human milk lipids. Specifically, Koletzko, et al. state that human milk from healthy and well-nourished mothers is the preferred form of feeding for all healthy newborn infants, and discuss the general characteristics of human milk lipids and recent knowledge on lactational physiology, composition, and functional aspects of human milk lipids. Koletzko, et al. state that the diet of lactating women influences, to some extent, the fatty acid composition of human milk lipids, and notes that biologically important long-chain polyunsaturated fatty acids (LC-PUFAs) in milk may originate from the maternal dietary intake, from maternal body stores, or from endogenous synthesis. Koletzko, et al. state that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies, and that some studies in preterm infants have indicated functional effects of DHA supply on electroretinogram recordings, development of visual acuity, and performance in psychometric tests relative to infants fed formulas which contain linoleic acid and alpha-linolenic acid, but without preformed LC-PUFA.

Significantly, however, Koletzko, et al. fail to disclose or suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by amended claim 1. Nor do Koletzko, et al. generally recognize or suggest that nutritional formulas comprising ARA and DHA increase lean body mass and reduce fat body mass. Rather, as noted above, Koletzko, et al. generally discuss the physiological aspects of human milk lipids, and note that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some **articulated reasoning** with some **rational underpinning** to support the legal conclusion of obviousness."<sup>10</sup> The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as

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<sup>10</sup> *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (emphasis added).



laid down in *Graham v. John Deere Co.* (383 U.S. 1, 148 USPQ 459 (1966)). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, applicants note that none of the cited references disclose or suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the purpose of increasing lean body mass and reducing fat body mass in the infant, as required by amended claim 1. At best, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, without findings of anthropometric growth faltering or inhibition. Nowhere, however, is there any suggestion that the formulas of O'Connor, et al. have any effect on body composition, such as increasing lean body mass and reducing fat body mass, or should be fed to an infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. Similar to O'Connor, et al., the Innis, et al. reference evaluated the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants, but failed to suggest that such formulas increase lean body mass and reduce fat body mass, or should be fed to an infant for this purpose. Additionally, as previously noted, the Koletzko, et al. reference generally discusses the physiological aspects of human milk lipids, and notes that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies, but fails to disclose or suggest that infant formulas including both ARA and DHA have any effect on lean body mass and fat body mass. Thus, the requirement in applicants' amended claim 1 that a nutritional formula comprising a source of DHA and ARA be fed

to an infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant is entirely lacking from the cited references.

Nor is there apparent reason for one skilled in the art to modify the cited references to arrive at applicants' claimed method. As recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc., while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs [caution as to] a patent application that claims as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the [art] to combine the elements in the way the claimed new invention does."<sup>11</sup>

As discussed in the specification of the instant application, applicants' have discovered that infants fed a nutritional formula comprising DHA and ARA, or a suitable source thereof, can increase lean body mass and reduce fat body mass as compared to an unsupplemented control formula, without having an impact on the rate of overall growth of the infant.<sup>12</sup> In contrast, none of the cited references disclose or recognize that the combination of DHA and ARA has any effect on body mass,

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<sup>11</sup> 2007 WL at 5.

<sup>12</sup> See Specification at p. 2, lines 13-16, and 24-27.

or more specifically can result in an increase lean body mass and a reduction in fat body mass in infants. Given this lack of disclosure and recognition, why would one skilled in the art modify the teachings of the cited reference to arrive at a method comprising feeding an infant a nutritional formula comprising a source of DHA and ARA for the specific purpose of increasing lean body mass and reducing fat body mass in the infant, as required in the method of Applicants' claim 1? There is simply no apparent reason to make this modification.

Accordingly, there is no articulated reason to combine or modify the teachings of the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 cannot be said to be obvious in view of the cited references.

In the Response to Arguments section of the current action, the Office has again stated that administering the same formula to the same population should produce the same results and, as such, even if the cited references do not literally disclose limitations relating to increasing lean body mass and reducing fat body mass in an infant, the references clearly teach that the formula enhances healthy growth. Applicants' respectfully disagree with the Office's position.

As noted above, amended claim 1 specifically requires a nutritional formula comprising a source of DHA and ARA be administered to an infant for the purpose of increasing lean body mass and reducing fat body mass in the infant. This limitation is not met merely by the disclosure of feeding a

nutritional formula comprising a source of ARA and DHA to an infant. Rather, there must be some disclosure in the cited references of a method wherein a nutritional formula comprising a source of DHA and ARA is administered to an infant for the specific purpose of increasing lean body mass and reducing fat body mass in the infant. Contrary to the Office's assertion, whether or not a nutritional formula comprising a source of DHA and ARA inherently results in an increase in lean body mass and a reduction in fat body mass when fed to an infant is irrelevant to determining if the cited references disclose or suggest applicants' claimed method. In the instant case, none of the cited references disclose or suggest that the combination of DHA and ARA has any effect whatsoever on lean body mass and fat body mass, much less suggest feeding an infant a nutritional formula comprising a source of DHA and ARA for the specific purpose of increasing lean body mass and reducing fat body mass in the infant.

In the Response to Arguments section of the current action, the Office has also stated that one of ordinary skill in the art knows that increasing lean body mass and reducing fat body mass is the healthiest type of growth. The Office goes on to state that Koletzko<sup>13</sup> teaches administering ARA and DHA in reasonable amounts to full-term infants because it is correlated to weight growth, and that there is an inverse relationship of total trans

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<sup>13</sup> Applicants assume the Office's comments relating to Koletzko is referring to the article entitled "Fatty acids and early human growth," (Am. J. Clin. Nutr., 2001, Vol. 73, p. 671-2), rather than the Koletzko, et al. article ("Physiological aspects of human milk lipids," Early Human Development, 2001, 65 Suppl.:S3-S18) that was cited in the §103 rejection.

fatty acids to concentrations of various essential fatty acids in plasma lipids of mothers and infants. The Office concludes that since it is reported that the combination of ARA and DHA reduces plasma content of fat and consequently the fat that reaches the cells, then it is expected that the growth correlated with the administration of ARA and DHA is achieved in protein content of the cells, i.e., mainly muscular tissue. Applicants respectfully disagree.

Initially, applicants respectfully submit that the Office appears to be misinterpreting the Koletzko reference. Specifically, contrary to the Office's assertion, Koletzko does not state that administration of ARA and DHA in reasonable amounts is correlated to weight growth of infants. Rather, Koletzko merely states that infant formulas with a balanced supply of dietary ARA and DHA in reasonable amounts did not lead to poor growth or other adverse effects in several randomized clinical trials.<sup>14</sup>

Furthermore, nowhere does Koletzko disclose or suggest that the combination of ARA and DHA reduces plasma content of fat, and consequently the fat that reaches cells. Rather, Koletzko merely describes a study in which the authors of the study report on an inverse relation of total *trans* fatty acids to concentrations of various essential fatty acids in plasma lipids of both mothers and infants. Koletzko states that these inverse correlations may reflect either potential inverse associations of dietary intakes of *trans* and essential fatty acids in the

mothers, reflecting their food choices, or the metabolic suppression of essential fatty acid desaturation by *trans* isomers. Koletzko does not, however, state that the essential fatty acids referred to in the study are ARA and DHA, or that the inverse relation of total *trans* fatty acids to concentrations of various essential fatty acids in plasma lipids results in a reduction of plasma content of fat or the fat that reaches cells, or in the reduction of fat body mass. Additionally, Koletzko indicates that firm conclusions on cause and effect cannot be drawn from correlations found in these observational studies, because several confounding factors may have influenced the results.<sup>15</sup>

Since Koletzko does not disclose that administering ARA and DHA to an infant increases weight growth or results in a reduction of plasma content of fat or the fat that reaches cells, or more particularly in the reduction of fat body mass, applicants submit that there is no apparent reason, based on the disclosure of Koletzko, for one skilled in the art to feed an infant a nutritional formula comprising a source of DHA and ARA for the specific purpose of increasing lean body mass and reducing fat body mass.

As claims 2-16 depend directly or indirectly from claim 1, claims 2-16 are patentable for the same reasons as claim 1, as well as for the additional elements they require.

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<sup>14</sup> See Koletzko at p. 672.

<sup>15</sup> See *id.*

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Furthermore, with regard to new claim 17, applicants note that none of the cited references disclose evaluating the lean body mass and fat body mass of an infant after feeding the infant a nutritional formula comprising a source of DHA and ARA. Claim 17 is thus also patentable over the cited references.

**CONCLUSION**

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-16 and allowance of all pending claims. The Commissioner is hereby authorized to charge the fee for the Request for Continued Examination filed herewith and any additional government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

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